***In re National Prescription Opiate Litigation*: MDL 2804**

Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude Meredith Rosenthal's Opinions and Proposed Testimony

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Concise Description of Issues:

***Issue* #1.** Are the opinions of Professor Rosenthal admissible under *Daubert* and FED. R. EVID. 702?

***Answer*:** Yes. Professor Rosenthal is unquestionably well-qualified as an expert, and courts have repeatedly admitted her testimony concerning causation in cases involving pharmaceutical marketing. She will offer opinions on a core issue in this case – the extent to which Defendants' marketing campaign caused an increase in prescription opioid sales over the relevant time period. To measure this, she performed a regression analysis, a methodology that courts have accepted in countless cases as a reliable means of measuring causation, and used data whose reliability Defendants do not challenge.

Defendants' primary argument in support of exclusion is that Professor Rosenthal's opinions do not "fit" Plaintiffs' theory of liability. This argument misconstrues and mischaracterizes Plaintiffs' theory of liability. Plaintiffs have alleged a nationwide campaign that was intended to and did increase the demand for prescription opioids. Because Plaintiffs have alleged, and will prove, that Defendants' marketing campaign polluted the entire prescribing ecosystem, Plaintiffs do not need to identify specific prescriptions written because of specific detailing visits, and an analysis of causation should not seek to isolate and disaggregate specific providers, but instead should be focused, as Professor Rosenthal's was, on the class of drugs at issue. Professor Rosenthal developed an aggregate model that captured the spillover effects across manufacturers and across drugs that Plaintiffs will show at trial. Professor Rosenthal developed her model to match what Plaintiffs alleged and will prove, rather than the case as framed by Defendants. Her assessment of causation will be helpful to the factfinder in assessing Plaintiffs' claims as they will actually be presented.

Defendants' arguments concerning the reliability of Professor Rosenthal's methodology fall similarly flat. Their criticisms of her aggregate model identify nothing that even remotely calls into question its reliability. Instead, they assert criticisms about her choice of variables that reflect a misunderstanding of the purpose of her model, or at best, go to the weight and not admissibility of her testimony, and are properly the subject of cross-examination. Professor Rosenthal's methodology is squarely within the mainstream of her field, and she provides ample support for each step that she took to develop the model and assess causation.

Filing Date: June 28, 2019

Response Date: July 31, 2019

Reply Date: August 16, 2019

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION	MDL 2804
OPIATE LITIGATION	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO MOTION TO EXCLUDE MEREDITH ROSENTHAL'S OPINIONS AND PROPOSED TESTIMONY

July 31, 2019

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INTRODUCTION

Defendants seek to exclude the testimony of Harvard health care economist Professor Meredith Rosenthal, but assert no valid basis to do so. Professor Rosenthal, whose testimony has been repeatedly admitted in pharmaceutical litigation over more than a decade, set out to measure a core issue in this case – the extent to which Defendants' marketing campaign caused an increase in prescription opioid sales over the relevant time period. She performed a regression analysis, a methodology that courts have repeatedly accepted in countless cases as a reliable means of measuring causation, and used data whose reliability Defendants do not challenge.

Unable to challenge Professor Rosenthal's qualifications or her choice of methodology, Defendants primarily challenge the "fit" between Plaintiffs' theory of liability and the testimony she will offer, but in doing so, mischaracterize Plaintiffs' theory of liability and describe a case that Plaintiffs did not bring. Plaintiffs have alleged a nationwide campaign that was intended to and did increase the demand for prescription opioids. Because Plaintiffs have alleged, and will prove, that Defendants' marketing campaign polluted the entire prescribing ecosystem, Plaintiffs do not need to identify specific prescriptions written because of specific detailing visits. Professor Rosenthal developed an aggregate model that captured the spillover effects across manufacturers and across drugs that Plaintiffs will show at trial. Professor Rosenthal developed her model to match what Plaintiffs alleged and will prove, rather than the case as framed by Defendants, and she made reasonable assumptions to fit Plaintiffs' claims. Her assessment of causation will be helpful to the factfinder in assessing Plaintiffs' claims as they will actually be presented.

When Defendants turn to Professor Rosenthal's methodology, they identify nothing that even remotely calls into question its reliability. Instead, they assert criticisms about her choice of variables that reflect a misunderstanding of the purpose of her model, or at best, go to the weight and not admissibility of her testimony, and are properly the subject of cross-examination. Professor

Rosenthal's methodology is squarely within the mainstream of her field, and she provides ample support for each step that she took to assess causation. The Court should deny Defendants' motion.

PROFESSOR ROSENTHAL'S METHODOLOGY AND OPINIONS

Dr. Meredith Rosenthal holds a Ph.D. in Health Policy (Economics Track). She is the C. Boyden Gray Professor of Health Economics and Policy at the Harvard T.H. Chan School Public Health, where she teaches undergraduate and graduate-level courses in health economics and health policy. She is the author or co-author of dozens of peer-reviewed publications healthcare economics and health policy. *See* Attachment A to Expert Report of Meredith Rosenthal, Dkt. No. 2000-23. She has provided expert testimony in more than a dozen litigations involving allegations of improper pharmaceutical marketing,[1] and courts overseeing complex pharmaceutical litigation have repeatedly admitted her testimony over *Daubert* challenges. *See, e.g., In re Neurontin Marketing & Sales Pracs. Litig.*, 712 F.3d 21 (1st Cir. 2013); *In re Solodyn Antitrust Litig.*, No. 14-md-2503, 2018 WL 563144 (D. Mass. Jan. 25, 2018); *U.S. ex rel. Bahnsen v. Boston Sci. Neuromodulation Corp.*, No. 11-1210, 2017 WL 6402633 (D.N.J. Dec. 15, 2017); *In re Actiq Sales & Marketing Pracs. Litig.*, No. 07-cv-4492, 2014 WL 3572932 (E.D. Pa. July 21, 2014); *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156 (1st Cir. 2009); *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571 (E.D.N.Y. 2007). Defendants do not challenge Professor Rosenthal's qualifications.

In this case, Professor Rosenthal's task was straightforward. First, using data on detailing contacts (visits to physicians and other providers, *see* Rosenthal Rep., Dkt. No. 2000-23, ¶ 56), she assessed the combined effects of the Defendant manufacturers' marketing on opioid sales in the bellwether communities. Second, she assessed "but for" causation -- whether the increase in the use of opioids would have occurred but for Defendants' allegedly unlawful promotion -- and the extent

[1] Professor Rosenthal identifies fourteen such litigations in her report. *See* Rosenthal Rep., Dkt. No. 2000-23, ¶ 2.

of such an increase. Finally, she determined whether she could draw conclusions about causation if one or more of the defendants is found not have engaged in unlawful marketing. *See id.* ¶ 8. Her work was informed by a detailed review of literature on pharmaceutical marketing, including what is known about marketing's effects on physicians (*see id.* at Section VI), and by a review of Defendants' own statements and documents reflecting their understanding about the efficacy of their marketing and promotion (*id.* at Section VII).

Professor Rosenthal's methodology in assessing causation was also straightforward – a time-series regression analysis. Countless courts have recognized regression analysis as a reliable means of testing causation. *See In re Neurontin*, 712 F.3d at 42 ("[R]egression analysis is a well recognized and scientifically valid approach to understanding statistical data, and courts have long permitted parties to use statistical data to establish causal relationships.") (collecting authority). She performed two separate regression analyses. The first was a "direct" approach, which modeled the impact of Defendants' promotion on opioid sales. Rosenthal Rep., Dkt. No. 2000-23, ¶¶ 49-77. The second was what she calls an "indirect" approach, which uses economic, demographic, and health care data on the county level to predict opioid sales given only changes in those factors, and thus permits an inference that Defendants' promotion caused higher sales. *See id.* ¶¶ 78-89. Professor Rosenthal also tested an alternative explanation for the dramatic increase in opioid prescribing between 1995 and 2018 -- the so-called "under-treatment" of pain. *See id.* ¶ 90.[2]

Professor Rosenthal found that, consistent with published literature and Defendants' internal documents, Defendants' promotional activities increased sales of opioids over the relevant time period. Under her direct method of estimation, she concludes that Defendants' promotion led to excess sales of 45 percent, and under her indirect method of estimation, Defendants' promotion

[2] Dr. Sherry Glied, a health economist and Dean of the Robert F. Wager Graduate School of Public Service of New York University, provides a careful assessment of Dr. Rosenthal's methodology in measuring the effect of Defendants' marketing, as well as Defendants' criticisms of that methodology. She finds that "the approach Professor Rosenthal has taken to this problem is reasonable and appropriate." Exh. 2, Declaration of Sherry Glied ("Glied Decl.") ¶ 8.

led to excess sales of 67 percent. *See id.* at 10 ("Summary of Opinions"). As for the alternative explanation of "under-treatment" of pain, Dr. Rosenthal found that increased sales over the relevant time period cannot be explained by clinical need. *See id.* ¶ 103. She also found that it is possible to remove particular defendants' promotional activities from her model and still provide estimates of the impact of remaining defendants' promotion. *See id.* ¶¶ 76-77.

ARGUMENT

I. PROFESSOR ROSENTHAL'S OPINIONS FIT PLAINTIFF'S THEORY OF LIABILITY.

A. Defendants Base Their "Fit" Arguments on a Mischaracterization of Plaintiffs' Theory of Liability.

Defendants lead off with their brief by arguing that Professor Rosenthal's opinions do not "fit" Plaintiffs' theory of liability because she set out to measure the effects of all detailing by Defendants, rather than isolate detailing to particular physicians and measure only that. Br. at 5. The Sixth Circuit has explained the "fit" requirement to mean that "expert testimony that does not relate to any issue in the case is not relevant and therefore not helpful." *U.S. v. Bonds*, 12 F.3d 540, 555 (6th Cir. 1993). Professor Rosenthal's testimony easily meets this standard.[3] Moreover, her choice of an aggregate analysis perfectly fits Plaintiffs' allegations.

Defendants' argument about "fit" is based on a mischaracterization of Plaintiffs' theory of liability in this litigation. Plaintiffs' theory of liability, clearly set forth in the operative complaint and later synthesized by this Court, is that Defendants employed a marketing strategy designed to increase the demand and market for opioids. Professor Rosenthal set out to measure the effects of that strategy. The fit could not be closer or more precise.[4]

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[3] By contrast, in *Botnick v. Zimmer, Inc.*, 484 F. Supp. 2d 715 (N.D. Ohio 2007), cited by Defendants (Br. at 3-4) the Court found a lack of fit where the expert in a product defect case "had no familiarity with the manufacturing processes which generated the Device, alternative designs, or the use of the Device in the marketplace." *Id.* at 721.

[4] Defendants' reliance (at 4 and 6) on *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227 (11th Cir. 2009), is misplaced. In that case, the Court faulted the expert for trying to "hang a baggy injury and damages theory" on a "trim-fitting liability theory." *Id.* at 1233. Here, while Defendants may disagree with the aggregate approach that Plaintiffs have taken to proving liability, there is no mismatch between the theory that Plaintiffs are pursuing and the one that Professor Rosenthal modeled.

Plaintiffs have consistently alleged that Defendants' conduct "contributed to an overall narrative that aimed to – and did – mislead doctors, patients, and payors about the risk and benefits of opioids." Third Am. Compl. ¶ 174. They alleged that the common purpose of the marketing enterprise was "to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain." *Id.* ¶ 880. In ruling on Defendants' motion to dismiss, the Court had no difficulty recognizing the theory of a nationwide campaign that "sought to dramatically increase sales," and to "reverse the long-settled understanding of the relative risks and benefits of opioids." ECF No. 1025 (Report and Recommendation), at 3 (citing Complaint); *see also id.* at 27 (stating that Plaintiffs alleged a "conspiracy to dramatically increase the usage and supply of opioids for off-label purposes"). Plaintiffs have repeatedly asserted, and will prove at trial, that all of Defendants' promotional activity was fraudulent because Defendants so thoroughly misrepresented the risks and benefits of opioids, and consistently omitted the true facts about tolerance, addiction, and withdrawal, that no doctor could make an appropriate prescribing decision. Plaintiffs have further explained that *every* opioid prescription written after Defendants' campaign to change the medical community's understanding of opioids took hold was infected by fraud and that this fraud affected not only *whether* to prescribe an opioid, but also at what dose, for what duration, with what warnings to the patient, and with what supervision for signs of misuse.

It has also long been clear that Plaintiffs intended to pursue that theory through an aggregate approach. *See* Order re Discovery Ruling #5 (noting that Plaintiffs "will rely, at trial and in expert opinions, solely on a theory of aggregate proof"). In addition, the availability of joint and several liability for Plaintiffs' claims, which also weighs in favor of an aggregate approach to measuring the impact of Defendants' promotional activities, has long been known to the parties. *See, e.g.,* Mot. of Pltfs.' Cuyahoga Cty. and Summit Cty. for Partial Summ. Adjudication of Their Equitable Claims for Abatement and of an Absolute Public Nuisance (filed June 28, 2019), at 22-23; *Capogreco v. Pro Ins.*

Agency, Inc., 2007 WL 4510266, at *9 (N.D. Ohio Dec. 18, 2007) (holding that RICO defendants are jointly and severally liable for damages) (citing *Fleischhauer v. Feltner*, 879 F.2d 1290, 1301 (6th Cir.1989)).

Professor Rosenthal's opinions directly fit Plaintiffs' theory. Defendants' assertion that Professor Rosenthal "does not purport to measure the effects of Defendants' allegedly unlawful conduct" (Br. at 5), ignores what Plaintiffs and this Court have said this case is about, which is a campaign of misrepresentations and omissions that polluted all opioid prescribing. Had Professor Rosenthal attempted to distinguish individual detailing visits from one another, or to identify particular prescriptions written as a result of individual detailing visits, as Defendants insist she should have, Defendants may have had a potentially valid argument about fit. But to point out that Professor Rosenthal did not separate lawful from unlawful detailing in measuring overall impact of Defendants' marketing is only to highlight the fit between her opinions and Plaintiffs' theory of liability.[5]

Professor Rosenthal herself provided ample explanation for her decision to apply an aggregate analysis to measure the impact of Defendants' promotion. Her report described a promotional ecosystem with pervasive spillover effects, through professional networks and peer-to-peer marketing acting "as a form of contagion" (Rosenthal Rep., Dkt. No. 2000-23, ¶ 25), and where unbranded marketing also affects sales. *See id.* ¶ 26 and generally Section VI(C). Her approach fit the facts of this case, which involves an *epidemic*, a term that "connotes the infectious nature of utilization, addiction, and harm," and that weighs against an approach that ignores the "infectious nature of promotion." Exh. 1, Declaration of Professor Meredith Rosenthal in Opposition to Defendants" Motion to Exclude My Opinions and Proposed Testimony ("Decl.") ¶¶ 11-12.

[5] Dr. Glied confirms that Dr. Rosenthal's model was appropriately tailored to answer the relevant question at hand – "How much did the detailing (or marketing) of drug X affect the number of prescriptions written for all opioids – that is, for the *class of drugs* that includes X?" Glied Decl. ¶ 16.

B. Professor Rosenthal's Use of Detailing to Assess Promotional Impact Is Reasonable and Well-Supported.

Defendants assert that Professor Rosenthal failed to account for the effects of Defendants' use of front groups, KOL's ("key opinion leaders"), and continuing medical education programs to advance their nationwide marketing campaign. *See* Br. at 7-8. They are mistaken. Professor Rosenthal's report explained why detailing is a reasonable proxy for other forms of promotion, and why data limitations made this focus necessary. *See* Rosenthal Rep., Dkt. No. 2000-23, ¶ 56 ("The Rationale for and Implications of Using Detailing as the Measure of Conduct"). While this focus was appropriate, Professor Rosenthal did not ignore other forms of marketing; Defendants neglect to mention that Professor Rosenthal performed a sensitivity analysis of third-party efforts that Defendants fault her for not including, and explained her rationale for not including them directly in her model. *See id.* ¶¶ 73-74. Her use of detailing data raises no problems of fit.

Professor Rosenthal provided three separate reasons for the focus on detailing as a measure of promotional efforts. First, it is "by far the dominant form of promotion." *Id.* Second, other forms of marketing tend to follow detailing, increasing or decreasing along with detailing so that, "From an econometric standpoint, detailing is a good proxy for total promotional effort." *Id.* Third, as Professor Rosenthal also explained, "alternative measures of promotion" have data limitations that would impair her ability to conduct a complete analysis. *Id.* If anything, removing the potential effects of other forms of promotion from Professor Rosenthal's direct model is conservative, *id.*, and should be welcomed by Defendants. Defendants will have an opportunity, through cross-examination, to raise questions about Professor Rosenthal's use of detailing in her model, but her use of the best available data to reach her conclusions is not a legitimate basis for exclusion. *See, e.g., In re Welding Fume Prods. Liab. Litig.*, 1:03–CV–17000, MDL 1535, 2005 WL 1868046, at *11 (N.D. Ohio Aug. 8, 2005) ("The Court easily concludes that any lacunas identified by defendants in … [the] expert report are grist for cross-examination, not the basis for wholesale exclusion.").

Defendants also misstate Professor Rosenthal's report and mischaracterize her opinions when they assert that under her direct model, "detailing alone explains 99 percent of all MME sales over the preceding two decades," and that other promotional activities "had no discernible effect." Br. at 7-8. This is incorrect for several reasons. First, Professor Rosenthal's model, as the deposition testimony cited by Defendants makes clear, explains 99 percent of the *variation* in MME sales over time, not "MME sales," as Defendants' brief contends. Second, Professor Rosenthal's model includes a price term as one among other factors other than detailing. *See* Rosenthal Rep., Dkt. No. 2000-23, ¶ 61; App. D. Further, as Professor Rosenthal explained, non-detailing activities complement detailing and will rise and fall together. *Id.* ¶ 56. Her model fits Plaintiffs' allegations.

C. Professor Rosenthal's Use of Aggregate Proof Is Appropriate.

Professor Rosenthal's use of an aggregate model to assess the effects of Defendants' marketing on opioid sales also presents no problems of fit. As set out above in Section I(A), that approach fits the theory of liability that Plaintiffs are pursuing, and the remedies they are seeking. Professor Rosenthal set out to answer the question of "to what extent did the conduct of these defendants affect the expansion of the use of opioids in the United States and in the specific bellwether counties." Meredith Rosenthal Dep. (5/4/19), Dkt. #1970-11, at 241:6-10. As she repeatedly explained, an aggregate model is far more reliable than the disaggregation that Defendants apparently urge in their motion in answering that question. "It smooths out variability in the data in ways that make the analysis more likely to show a true effect. It also overcomes certain data challenges … where if we only focused on those physicians who were detailed versus those were not, we might get the wrong results." *Id.* at 241:15-22; *see also id.* at 142:12-14 (aggregate model "cuts down on certain kinds of noise" and avoids "certain kinds of endogeneity problems"); 196:19-24 (aggregate model captures "substantial spillover effects" in Defendants' marketing) 80:16-19 (model was intended to capture "spillover effects").

Defendants' arguments against an aggregate approach do not withstand scrutiny. They claim that "Rosenthal's opinions also should be excluded because her model does not connect any particular Defendant's alleged misconduct to any opioid prescription that Plaintiffs claim such misconduct caused." Br. at 8. But Defendants do not explain why Professor Rosenthal should do so, other than to assert that the assignment of liability is something "her testimony presumably should address." *Id.*; *see also* Pltfs.' Consol. Mem. Opp. to Defs.' Mots. For Summ. J. on Proof of Causation (addressing apportionment).

Defendants also complain that because "Rosenthal's models do not allow her to assign liability to individual manufacturers," her model does not "assist the fact-finder in identifying which (if any) prescriptions were caused or written by any particular Defendant's allegedly false marketing." *Id.* at 9. But this Court has already held that RICO claims are not "rendered deficient by the failure to specifically identify a prescribing physician who relied on Defendants' alleged fraudulent statements." Report and Recommendation on Motion to Dismiss (ECF No. 1025), at 30. The Court then went on to quote extensively from the First Circuit's opinion in *In re Neurontin*, 712 F.3d 21, where the Court carefully reviewed Professor Rosenthal's testimony admitted in a pharmaceutical marketing case involving RICO claims. At trial, Professor Rosenthal used "aggregate data and statistical approaches to link patterns in promotion spending to patterns in prescribing for the drug," using the same regression analysis to present a "causal connection between the fraudulent marketing and the quantity of prescriptions written for off-label indications." *Id.* at 31 (quoting *Neurontin*, 712 F.3d at 29-30). As the Report and Recommendation summarized, she explained why "Pfizer's proposed physician-by-physician analysis of causation was not a scientifically valid approach to causation." *Id.* (quoting *Neurontin*). Rosenthal provided the same analysis here, showing why physician self-reporting is notoriously unreliable. *See* Rosenthal Rep., Dkt. No. 2000-23, ¶ 29.

Defendants ask this Court to re-tread this same ground, and invite this Court to approve the same flawed approach to causation that the First Circuit carefully considered and rejected.[6] Defendants do not address *Neurontin* in this section of their brief, but instead cite only two cases for the proposition that an expert must identify specific prescriptions caused by the unlawful conduct. *See* Br. at 9. The first case, *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 94 (2d Cir. 2015), has no applicability here. In that case, Professor Rosenthal did not perform a regression analysis, which the Court noted may have supported causation. *Id.* at 96. In fact, the Court specifically *declined* to hold that the type of regression analysis that Professor Rosenthal performed here (and in *Neurontin*), using aggregate data, would be insufficient: "[W]e need not (and do not intend to) express any view here on whether or when an aggregate regression analysis similar to the one deployed in *Neurontin* might be sufficient to prove causation on a class-wide basis in other pharmaceutical-marketing cases alleging a pattern of mail fraud actionable under RICO." *Id.* at 97. The second, *Petre v. Norfolk S. Ry. Co.*, 458 F. Supp. 2d 518, 543 (N.D. Ohio 2006), is far afield. It is a railway accident case that did not even involve admissibility of expert testimony.

Finally, Defendants' assertion that Professor Rosenthal's model would "break down if it were disaggregated by drug, by manufacturer, by detailing content, by detailing duration, or by any other basis less than opioid-class level" is not accurate, and that contention is not supported in the deposition testimony that Defendants cite. Br. at 10. For example, in the first portion of testimony cited, Professor Rosenthal explained that the aggregate approach was *more* reliable than an individual manufacturer approach "because there can be noise in the data when we try to disaggregate it too much." Rosenthal Dep., Dkt. #1970-11, at 196:22-25. Additionally, Professor Rosenthal

[6] Other courts have repeatedly allowed expert testimony that relied on aggregate models. *See, e.g., Chen-Oster v. Goldman, Sachs & Co.*, 325 F.R.D. 55, 71 (S.D.N.Y. 2018) (noting "statistical pitfalls of disaggregation"); *see also In re Pharm. Indus. Avg. Wholesale Price Litig.*, 582 F.3d at 197-98 (approving use of aggregate damages, and stating, "The use of aggregate damages calculations is well established in federal court and implied by the very existence of the class action mechanism itself.").

demonstrated that she is able to back out particular defendants from her model and still calculate overall impact. *See* Rosenthal Rep., Dkt. No. 2000-23, at 52 (Table 3).

II. PROFESSOR ROSENTHAL'S METHODOLOGY IS RELIABLE.

A. Professor Rosenthal's Assumptions Are Reasonable.

In addition to mischaracterizing Plaintiffs' theory of liability to argue for a lack of "fit," Defendants lodge a series of criticisms of Professor Rosenthal's methodology that proceed from a misunderstanding of how that methodology works, what it shows, and how it is relevant to Plaintiffs' claims. Defendants make no legitimate criticism of the methodology that Professor Rosenthal used. Instead, they argue for a different approach, or criticize particular choices of variables for her model. Those criticisms go to the weight, and not admissibility, of Professor Rosenthal's testimony.[7]

First, Defendants' insistence that Professor Rosenthal should have "evaluat[ed] the substance and context" of each detailing visit (Br. at 6) reflects Defendants' view that Plaintiffs must ignore the large-scale marketing campaign that they have alleged, and whose effects Professor Rosenthal has measured, in favor of anecdotes and physician self-reporting that have been long established, as Professor Rosenthal's report details, to be unreliable. *See* Rosenthal Rep., Dkt. No. 2000-23, ¶ 29. Rather than focus on individual detailing visits, Professor Rosenthal instead reasonably focused on what the overall volume of detailing revealed about physician behavior and prescribing. Her model is intended to, and does, capture the average effect of all detailing. *See, e.g.,* Rosenthal Dep., Dkt. #1970-11, at 205:23-25. *See also* Glied Decl. ¶ 19 (rejecting objection that Professor Rosenthal did not consider individual physician characteristics in her analysis).

[7] Plaintiffs' expert economists fully endorsed Professor Rosenthal's work as sound and reliable. David Cutler Dep. (04/26/19), Dkt. #1961-9 at 174:23-11, 187:11-15; Thomas G. McGuire Dep. (4/23/19), Dkt. #1966-21, at 204:11-15; 205:15-19. Dr. Cutler testified that Professor Rosenthal's model meets the standard for submission to an academic journal. Cutler Dep., Dkt. #1961-9, at 436:7-15.

Complaints like this one, about the particular inputs into a regression model, go to the weight, and not admissibility, of her testimony. *See Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 182 (6th Cir. 2009) (holding that where an expert's overall methodology is sound, "[a]ny weaknesses in his methodology will affect the weight that his opinion is given at trial, but not its threshold admissibility."). The Seventh Circuit has emphasized that this is especially true for courts evaluating regression analyses. *See Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 808 (7th Cir. 2013) ("[The Supreme Court and this Circuit have confirmed on a number of occasions that the selection of the variables to include in a regression analysis is normally a question that goes to the probative weight of the analysis rather than to its admissibility."); *see also In re Mushroom Direct Purchaser Antitrust Litig.*, No. 06-md-0620, 2015 WL 5767415, at *6 (E.D. Pa. July 29, 2015) (noting that "economics and statistics require the use of professional judgment, [so] expert testimony [in those fields] is less likely to be excluded because challenges may ultimately be viewed as matters in which reasonable experts may differ.") (internal quotation and citation omitted, alterations in original).[8] Further, as Dr. Glied points out, Defendants' own experts did not "identify available variables that could be added to" Dr. Rosenthal's that would alter her conclusions. *See* Glied Decl. ¶ 11.

Second, in another argument about a particular input, Defendants criticize Professor Rosenthal for including in her analyses detailing to providers who are hospice specialists for end-of-life care. Br. at 7. But the inclusion of such detailing does not remotely make Professor Rosenthal's methodology unreliable. As she explained in her deposition, her model would take into account the possibility that some detailing did not produce change in prescribing -- "it reduces the incremental effectiveness of promotion that I observe, and therefore, the calculated impact." Rosenthal Dep. (5/5/19), Dkt. #1970-12, at 737:7-10.

[8] This reasoning applies with equal force to Defendants' tacked-on criticism of Professor Rosenthal's indirect model. *See* Br. at 17-18. Defendants make no showing that the inclusion of any of the variables they suggest would have altered the findings of that model, and include suggested variables that Plaintiffs allege were affected by Defendants' misconduct, such as medical guidelines, physicians' prescribing habits, patient preference, and "loyalty to certain classes of drugs," and as such should not be treated as independent factors in any analysis of the effect of marketing on sales.

Finally, Defendants criticize Professor Rosenthal for including detailing that Defendants contend was "solely 'rivalrous.'" Br. at 7. This, too, misses the mark. As Professor Rosenthal explained in her deposition, she found that "the market expansion effects were important, whether or not there was also rivalry." Rosenthal Dep., Dkt. #1970-11, at 90:24-91:2. When asked again about a manufacturer "only engaged in rivalrous marketing," she rejected "the conceptual premise," and explained that "there will be market-increasing spillovers even from purely rivalrous marketing." *Id.* at 91:4-5, 9-12, 22-24. Her model appropriately captures those effects. Defendants are again arguing the case they wish Plaintiffs had brought, rather than the one that will be tried.

B. Professor Rosenthal Appropriately Assumed That All Manufacturer Promotion Would Be Shown To Be Unlawful.

To ensure that her analysis fit Plaintiffs' theory of liability, when applying the results of her model, Professor Rosenthal assumed that all of Defendants' promotion of opioids was unlawful. *See, e.g.*, Rosenthal Rep., Dkt. No. 2000-23, ¶ 11 ("The alleged unlawful promotion of opioids, if proven, resulted in increased sales of opioids."); ¶ 75 (explaining concept of "but for" causation). Defendants repeatedly attempt to fault Professor Rosenthal for that assumption, but there is nothing unusual about Professor Rosenthal's assumption that Plaintiffs will prove that Defendants' marketing campaign as a whole was unlawful, and thus not distinguish among detailing contacts in her model.[9] Experts routinely offer opinions based on the assumption that the factfinder will determine that the conduct at issue is unlawful. *See, e.g., In re Neurontin*, 712 F.3d at 30 ("As is customary for such experts, Dr. Rosenthal testified that she 'assumed that the allegations in the complaint are true' for purposes of conducting her analysis, but offered no view as to whether or not there had been a fraudulent marketing scheme.").[10] Although Defendants assert that the

[9] Professor Rosenthal also showed that her model could be adjusted to reflect the removal of individual defendants' marketing efforts. *See* Rosenthal Rep., Dkt. No. 2000-23, ¶¶ 76-77.

[10] Experts, including damages experts, assume liability for purposes of their analyses as a matter of course. *See, e.g., Robroy Industries–Texas, LLC v. Thomas & Betts Corp.*, No. 15-cv-512, 2017 WL 1319553, at *5 (E.D. Tex. Apr. 10, 2017) (holding that the principle that damages experts may assume liability "has been expressed in numerous cases, and it is beyond serious challenge") (collecting authority).

assumption that all manufacturer promotion lacks factual support (Br. at 10), as the Sixth Circuit has explained, where "facts" challenged by defendant were "not scientific facts to be evaluated under *Daubert*, but are rather the central questions of liability in the case," the questions are properly presented to the jury. *Avery Dennison Corp. v. Four Pillars Enterprise Co.*, 45 Fed. App'x. 479, 487 (6th Cir. 2002).[11] Nor did Professor Rosenthal "blindly" assume the unlawfulness of Defendants' marketing; she noted one defendant's guilty plea, and that executives of another were then facing criminal liability relating to fraudulent marketing. *See* Rosenthal Rep., Dkt. No. 2000-23, ¶ 47.

Plaintiffs have also identified sufficient facts to support the assumption. *See* Pltfs.' Joint Mem. Opp. to Summ. J. on Proof of Causation. Further, Defendants' assertion that Professor Rosenthal "assumes that it is unlawful for a Defendant manufacturer's sales representative to do nothing more than relay information from an in FDA-approved package insert or corrective statements" (Br. at 10) is counter-factual and mischaracterizes her opinions. There is no evidence that any of Defendants' detailing was limited in this way, or that it did not in all instances build on prior misrepresentations about the risks and benefits of opioids. Moreover, even if this occurred, as Prof. Rosenthal explained in her deposition in response to a question about "corrective messaging," her model is captures all detailing and its effects, which would include capturing declining effects. As she explained, after noting that "effective promotion is declining" in the last time period in her model, "To the extent that there's corrective messaging, that may be one of the factors that is decreasing the effectiveness of promotion…" Rosenthal Dep., Dkt. #1970-11, at 217:1-8.

[11] Defendants cite *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134 (E.D. Penn. 2015), for the proposition that Professor Rosenthal should not have followed counsel's instruction to assume that Defendants' promotion was unlawful, but that case is inapplicable. The opinion in that case concerned class membership; the Court had previously found that Professor Rosenthal presented a viable method for determining antitrust impact. *See id.* at 146. *Steyck v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002), also cited by Defendants, is also of no help. There, the Court affirmed the district court's decision to admit expert testimony, and reaffirmed the principle that cross-examination is the proper method to explore an opponent's expert's assumptions.

C. Professor Rosenthal's Opinions Concerning the Effects of Promotion Over Time Are Well Supported.

Defendants make a sweeping assertion that Professor Rosenthal "contorted and 'overfit' her model" to ensure her conclusions, but directly criticize only one aspect of her proposed testimony -- that the effects of opioid marketing will continue to increase over time. *See* Br. at 11. Far from "illogical," as Defendants contend, Professor Rosenthal's opinions about the snowballing effects of opioid marketing are well-supported, while Defendants' criticisms ignore the specific facts of this case and the nature of the opioid epidemic. Like the other items on Defendants' laundry list of criticisms, these criticisms are appropriately the subject of cross-examination.

Professor Rosenthal explained the basis for assuming a "negative depreciation" rate for opioid marketing in her report and in her deposition. In her report, she noted that a negative depreciation rate for opioid marketing is "perfectly consistent with an addictive product like opioids." Rosenthal Rep., Dkt. No. 2000-23, ¶ 72. Citing Plaintiffs' marketing expert, Dr. Matthew Perri III, she pointed out that as opioids "may result in tolerance, dependence and/or addiction, the overall 'demand' for opioids is distorted by pharmaceutical marketing aimed at increasing the use of these drugs." *Id.* n.103 (quoting Perri Rep. ¶ 32). Thus, "whether due to tolerance, dependence, or addiction, some patients who use opioids require and/or seek more opioids over time." *Id.* But Professor Rosenthal did not merely assume a negative depreciation rate for detailing; she designed her model to determine how long-lasting Defendants' promotional efforts were, using the stock of promotion as an explanatory variable over time. Rosenthal Rep., Dkt. No. 2000-23, ¶¶ 68-71; Decl. ¶¶ 30-33. Thus, she *found* negative depreciation, she did not assume it. *See also* Glied Decl. ¶¶ 20-22 (explaining that Dr. Rosenthal's model "appropriately attributes persistence in opioid use to prior opioid marketing").

The increase in the use of opioids over time is far from mere speculation; it is an observable fact, as Professor Rosenthal explained in her deposition. As she testified, "It is clearly true that patients who started on a particular dose of opioids get higher and higher doses," Rosenthal Dep.,

Dkt. No. 1970-11, at 250:17-19, and pointed to her report, which includes an illustration of escalating dosages over time. *Id.* at 252:7-9; Rosenthal Rep., Dkt. No. 2000-23, at Fig. 3 (at ¶ 54).[12] Defendants offer no alternative explanation to increasing tolerance and addiction for this phenomenon. Elsewhere in her report, Professor Rosenthal reviews academic literature on pharmaceutical marketing and notes the consensus that "promotional effects are long-lived." *Id.* ¶ 33.[13]

By contrast, to support the contention that apparently all marketing effects fade over time, Defendants attach a study from 1982 that was not a market-level analysis, nor focused on pharmaceutical marketing, let alone an addictive substance. *See* Br. at 12. Defendants cite the testimony of their own expert, Dr. Grabowski, that he had not seen a negative depreciation rate. Br. at 11-12. However, the literature he cites in his report either did not estimate a marketing depreciation rate at all, or involved direct-to-consumer marketing, or did not involve class-level (as opposed to brand-product level) marketing. *See* Decl. ¶¶ 41-49. Even with that wan challenge, Defendants have merely identified a disputed fact issue. As the Sixth Circuit has long held, "where the opinion has a reasonable factual basis, it should not be excluded. Rather, it is up to opposing counsel to inquire into the expert's factual basis." *U.S. v. L.E. Cooke Co., Inc.*, 991 F.2d 336, 342 (6th Cir. 1993) (quoted in *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 530–31 (6th Cir. 2008)).

Defendants assert that Professor Rosenthal's direct model "contains so much flexibility" that unrelated events, such as sunspots or Cleveland Indian baseball game attendance, could show a causal relationship to physician detailing (Br. at 12-13), but that argument relies on blatant cherry-picking, and does not withstand even basic scrutiny. For example, to show a causal relationship

[12] Defendants make no objection to the data underlying Figure 3, or to the reliability of any of the data that Professor Rosenthal uses for her analyses.

[13] With Professor Rosenthal having set forth the bases for her opinion about the persistent effects of pharmaceutical marketing generally and opioid marketing specifically, Defendants' citation of *Ashland Hosp. Corp. v. Affiliated FM Ins. Co.*, 2013 WL 3213051 (E.D. Ky. June 24, 2013), is misplaced. There, the expert provided no study, report, or source supporting his opinions, and pointed to no instances of any other expert in his field employing his theory. *Id.* at *6.

between sunspots and physician detailing, Dr. Kyle selected a specific window of 179 months to produce an R-squared value of 85 percent. However, using all available data, any purported causal relationship disappears, while using 25 randomly selected windows of 305 months results in R-square values from 26 to 67 percent. *See* Decl. ¶¶ 51-53. Dr. Kyle simply picked a window that best fit Defendants' argument. Defendants' "placebo" exercise reveals nothing about the reliability of the model that Professor Rosenthal put forward here using price and promotion as explanatory variables, choices based on a sound theoretical and empirical foundation.

Finally, Defendants' statement that Professor Rosenthal's model "does not accurately predict real-world events that may have influenced opioid prescribing" such as a particular statement from the American Pain Society ("APA") or the reclassification of hydrocodone (Br. at 13), again misunderstands what her aggregate model is intended to do. She did not set out to measure the effects of individual events, especially those that relate to a single drug (hydrocodone), but instead to assess Defendants' efforts within an overall prescribing environment. Further, to the extent that a change in medical standards (such as the APA's statement) is the product of Defendants' misconduct, then such a change is appropriately not treated as a variable to be included in the analysis. *See* Decl. ¶ 55. Defendants' other suggested variables are irrelevant. *See id.* ¶ 56.

III. DEFENDANTS' OTHER CRITICISMS FAIL.

A. Professor Rosenthal's Simulation Concerning Purported "Under-treatment" of Pain Is Helpful and Relevant.

Finally, Defendants attack as unreliable Professor Rosenthal's simulation, in which she tested the hypothesis that previous under-treatment of pain could explain the rise of opioid sales is unreliable. This simulation, which she also called a "thought experiment," relates to a key disputed issue, and because it buttresses her conclusions stemming from the direct and indirect models, makes her opinions more robust and reliable, not less. *See* Rosenthal Rep., Dkt. No. 2000-23, ¶ 103 (noting that "nesting of these results as predicted bolsters the reliability of each").

Defendants overreach in their criticisms of this simulation. It is simply not true, as Defendants assert, that Professor Rosenthal "created her own" methodology to test the premise of under-treatment. Br. at 15. She repeatedly explained that what she conducted was a simulation, which she described as a "pretty common approach, particularly when it comes to looking at the effects of policies, proposed policies." Rosenthal Dep., Dkt. No. 1970-12, at 622:19-21. She provided three of her own publications that involved the same type of exercise (*id.* at 623:1-624:21), and, contrary to Defendants' misleading assertion that she could not identify "a single treatise or methodological paper supporting the work" (Br. at 15), she explained that the methodological frameworks for simulations like this are "likely context specific." Rosenthal Dep., Dkt. No. 1970-12, at 627:16-18.

Defendants then attack Professor Rosenthal's reliance on other experts for purposes of conducting this simulation. But such reliance by one expert like Professor Rosenthal, who is not a clinician, on another, is routinely accepted. *See In re: E.I. Du Pont De Nemours & Co. C-8 Personal Injury Litig.*, 337 F. Supp. 3d 728, 743 (S.D. Ohio 2015) ("An expert is able to base an opinion on another expert witness for a point of expert knowledge not personally possessed."); *Buck v. Ford Motor Co.*, 810 F. Supp. 2d 815, 844 (N.D. Ohio 2011) ("[A]n expert's testimony may be formulated by use of the facts, data, and conclusions of other experts.") (internal quotation omitted). And while Defendants note that Plaintiffs have withdrawn the proposed testimony of one of the experts, Dr. Parran, whose work Professor Rosenthal consulted, Professor Rosenthal testified that she did not "believe any of the assumptions were solely based on Dr. Parran," Rosenthal Dep., Dkt. No. 1970-12, at 634:1-2, and pointed out that she had looked not just to other experts, but also a number of guidelines and articles. *Id.* at 629:7-10. Her reliance on these experts raises no admissibility concerns at all. *See Ohio Envtl. Dev. Ltd. P'ship v. Envirotest Sys. Corp.*, 478 F. Supp. 2d 963, 974-75 (N.D. Ohio 2007) ("If an expert's consultation of another expert's opinion is a resource 'reasonably

relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted.'") (citing Fed. R. Evid. 703).

B. Professor Rosenthal Did Not Ignore Stationarity or Endogeneity.

Defendants conclude their brief with a grab bag of additional arguments about Professor Rosenthal's model. These arguments also go to the weight, and not admissibility, of Professor Rosenthal's testimony. They are also unfounded.

First, Defendants misleadingly assert that Professor Rosenthal "made no effort to test for or correct any nonstationarity." Br. at 16. In fact, Professor Rosenthal explained that she anticipated the potential problem of spurious correlation of trends over time, performed a unit root test, and found no such problem. Rosenthal Dep., Dkt. No. 1970-11, at 137:8-23; 139:25-140:4. Defendants' motion makes no showing that Professor Rosenthal's model has any issues regarding stationarity; it does not even cite to their own experts who offered opinions on unit roots, because neither expert properly identified any such problem with Professor Rosenthal's work. *See* Decl. ¶¶ 57-66.

Second, Defendants assert that Professor Rosenthal did not test for endogeneity, or the potential correlation between the explanatory variable (detailing) and dependent variable (opioid sales). Br. at 17. Defendants' motion simply asserts, citing no data or even opinions from their own experts, that Professor Rosenthal's model has an endogeneity bias. But Professor Rosenthal explained at length in her deposition why testing for endogeneity is not appropriate in a model assessing multiple products, or here, multiple drugs. *See* Rosenthal Dep., Dkt. No. 1970-11, at 142:25; 332:21-333:25. Endogeneity is only a potential concern when the dependent variable is contemporaneous with the explanatory variable, but in an aggregate model, that is not a concern, because with so much variation in detailing across time, aggregate detailing would not be determined by aggregate sales. *See* Decl. ¶¶ 73-78. Finally, Defendants' assertion that tests for endogeneity "exist" but not used here is misleading. In fact, in the deposition testimony that Defendants cite,

defense counsel asked Professor Rosenthal about the use of those tests in other litigation involving a single drug. *See* Br. at 17 (citing Rosenthal Dep. at 337:22-338:4). Defendants' attacks on Professor Rosenthal's methodology are wide of the mark.

CONCLUSION

For these reasons, Defendants' motion should be denied.

Dated: July 31, 2019

Respectfully submitted,
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